

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 134687NV (MHM 15085US01)

In the Application of:)	
)	
Peterson)	<u>Electronically Filed On January 14, 2009</u>
)	
Serial No.: 10/660,825)	
)	
Filed: September 12, 2003)	
)	
For: SYSTEM AND METHOD FOR)	
DETERMINING THE POSITION OF A)	
FLEXIBLE INSTRUMENT USED IN A)	
TRACKING SYSTEM)	
)	
Examiner: Mehta, Parikha Solanki)	
)	
Group Art Unit: 3737)	
)	
Confirmation No.: 7037)	

APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Applicant respectfully requests that the Board of Patent Appeals and Interferences reverse the rejection of claims 1-23 of the present application. The Appeal Brief is timely because it is being filed with a Notice of Appeal within three months of the November 18, 2008 Office Action.

REAL PARTY IN INTEREST
(37 C.F.R. § 41.37(c)(1)(i))

The real party in interest is GE Medical Systems Global Technology Company, having a place of business at 3000 North Grandview Boulevard, Waukesha, Wisconsin 53188.

RELATED APPEALS AND INTERFERENCES
(37 C.F.R. § 41.37(c)(1)(ii))

Not applicable.

STATUS OF THE CLAIMS
(37 C.F.R. § 41.37(c)(1)(iii))

The present application includes claims 1-23, all of which stand rejected.¹ The Applicant identifies claims 1-23 as the claims that are being appealed. The text of the claims involved in this Appeal, namely, claims 1-23, is provided in the Claims Appendix.

STATUS OF AMENDMENTS
(37 C.F.R. § 41.37(c)(1)(iv))

A Final Office Action rejecting claims 1-23 was mailed on November 18, 2008. In response to that Final Office Action, the Applicant is filing a 2nd Notice of Appeal and this Appeal Brief.

¹ See November 18, 2008 Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER
(37 C.F.R. § 41.37(c)(1)(v))

Independent claim 1 recites the following:

A medical instrument² for use in an image guided surgery system,³ comprising:
a support member⁴ operatively connected to a flexible engaging member⁵ having an operative distal tip;⁶ and
a strain gauge⁷ affixed to an outer portion of said flexible engaging member,⁸ wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member.⁹

Dependent claim 2 recites the following:

The medical instrument of claim 1, wherein a resistance of said strain gauge changes when said flexible engaging member deflects.¹⁰

Dependent claim 3 recites the following:

The medical instrument of claim 2, wherein said strain gauge¹¹ is within an electrical

² See present application, *e.g.*, at page 8, lines 4-5 and Figures 1, 5 and 6, ref. 10.

³ See *id.*, *e.g.*, at page 5, lines 2-3.

⁴ See *id.*, *e.g.*, at page 5, lines 3-4, page 8, lines 5-7 and Figure 1, ref. 12..

⁵ See *id.*, *e.g.*, at page 5, lines 5-11, page 8, line 20 to page 9, line 4, Figure 1, ref. 14 and Figure 2, ref. 26.

⁶ See *id.*, *e.g.*, at page 5, lines 7-8 and Figure 1, ref. 17.

⁷ See *id.*, *e.g.*, at page 5, lines 4-5, page 8, lines 12-19, page 8, line 20 to page 9, line 23, Figures 1, 5 and 6, refs. 16 or 18 and Figures 2-3, refs. 28 or 30.

⁸ See *id.*, *e.g.*, at page 5, lines 4-5, page 8, lines 12-18 and Figures 1, 5 and 6, refs. 16 or 18.

⁹ See *id.*, *e.g.*, at page 5, lines 5-9, page 8, lines 13-14 and page 9, line 9 to page 12, line 8.

¹⁰ See *id.*, *e.g.*, at page 9, lines 9-23.

¹¹ See *id.*, *e.g.*, at page 10, lines 1-11 and Figures 4, refs. 28 or 30.

circuit¹² in which a potential difference occurs when said resistance of said strain gauge changes.¹³

Dependent claim 4 recites the following:

The medical instrument of claim 1, wherein said flexible engaging member is one of a needle, catheter, curette, and K wire.¹⁴

Dependent claim 5 recites the following:

The medical instrument of claim 1, further comprising at least one additional strain gauge affixed to said flexible engaging member.¹⁵

Dependent claim 21 recites the following:

The medical instrument of claim 1, wherein said strain gauge provides information regarding a location of said operative distal tip in relation to a longitudinal axis of said support member.¹⁶

Independent claim 7 recites the following:

An image guided surgery system,¹⁷ comprising:

a medical instrument¹⁸ having a flexible engaging member¹⁹ operatively connected to a

¹² See *id.*, e.g., at page 10, lines 1-11 and Figure 4, ref. 42.

¹³ See *id.*, e.g., at page 10, lines 1-11.

¹⁴ See *id.*, e.g., at page 5, lines 14-15 and page 8, lines 9-11.

¹⁵ See *id.*, e.g., at page 5, lines 15-16, page 12, lines 9-14 and Figure 5, refs. 16, 18 and 46.

¹⁶ See *id.*, e.g., at page 5, lines 5-9, page 8, lines 13-14, page 9, line 9 to page 12, line 8 and Figure 1, refs. 12, 14, 15, 16, 17, 18 and 20..

¹⁷ See *id.*, e.g., at page 12, line 9 to page 14, line 6.

¹⁸ See *id.*, e.g., at page 8, lines 4-5 and Figures 1, 5 and 6, ref. 10.

¹⁹ See *id.*, e.g., at page 5, lines 5-11, page 8, line 20 to page 9, line 4, Figure 1, ref. 14 and Figure 2, ref. 26.

support member,²⁰ said flexible engaging member having a deflectable operative distal tip;²¹

at least one of an electromagnetic, optical, inertial position, and ultrasound tracking system configured to track said medical instrument;²² and

a deflection tracking system²³ configured to track said flexible engaging member of said medical instrument, said deflection tracking system comprising at least one strain gauge²⁴ affixed to an outer portion of said flexible engaging member²⁵ in order to detect movement of said deflectable operative distal tip.²⁶

Dependent claim 8 recites the following:

The image guided surgery system of claim 7, wherein a resistance of said at least one strain gauge changes when said flexible engaging member moves.²⁷

Dependent claim 9 recites the following:

The image guided surgery system of claim 8, wherein said at least one strain gauge²⁸ is within an electrical circuit²⁹ in which a potential difference occurs when said resistance of said

²⁰ See *id.*, e.g., at page 5, lines 3-4, page 8, lines 5-7 and Figure 1, ref. 12.

²¹ See *id.*, e.g., at page 5, lines 7-8 and Figure 1, ref. 17.

²² See *id.*, e.g., at page 12, lines 15-22, page 13, lines 7-8 and Figure 6, ref. 100.

²³ See *id.*, e.g., at page 5, lines 4-5, page 8, lines 12-19, page 8, line 20 to page 9, line 23, Figures 1, 5 and 6, refs. 16 or 18 and Figures 2-3, refs. 28 or 30.

²⁴ See *id.*, e.g., at page 5, lines 4-5, page 8, lines 12-19, page 8, line 20 to page 9, line 23, Figures 1, 5 and 6, refs. 16 or 18 and Figures 2-3, refs. 28 or 30.

²⁵ See *id.*, e.g., at page 5, lines 4-5, page 8, lines 12-18 and Figures 1, 5 and 6, refs. 16 or 18.

²⁶ See *id.*, e.g., at page 5, lines 5-9, page 8, lines 13-14 and page 9, line 9 to page 12, line 8.

²⁷ See *id.*, e.g., at page 9, lines 9-23.

²⁸ See *id.*, e.g., at page 10, lines 1-11 and Figures 4, refs. 28 or 30.

²⁹ See *id.*, e.g., at page 10, lines 1-11 and Figure 4, ref. 42.

strain gauge changes.³⁰

Dependent claim 12 recites the following:

The image guided surgery system of claim 7, wherein said flexible engaging member is one of a needle, catheter, curette, and K wire.³¹

Dependent claim 22 recites the following:

The image guide surgery system of claim 7, wherein said at least one strain gauge provides information regarding a location of said deflectable operative distal tip.³²

Independent claim 14 recites the following:

A method of navigating³³ a medical instrument³⁴ having a flexible engaging member³⁵ having an operative distal tip,³⁶ the method comprising:

tracking the medical instrument with a first position tracking method³⁷ that tracks a proximal end of the medical instrument;³⁸ and

using a second tracking method³⁹ to track movement of the operative distal tip of the

³⁰ See *id.*, e.g., at page 10, lines 1-11.

³¹ See *id.*, e.g., at page 5, lines 14-15 and page 8, lines 9-11.

³² See *id.*, e.g., at page 5, lines 5-9, page 8, lines 13-14, page 9, line 9 to page 12, line 8 and Figure 1, refs. 12, 14, 15, 16, 17, 18 and 20.

³³ See *id.*, e.g., at page 5, lines 18-19 and page 14, lines 7-22.

³⁴ See *id.*, e.g., at page 8, lines 4-5 and Figures 1, 5 and 6, ref. 10.

³⁵ See *id.*, e.g., at page 5, lines 5-11, page 8, line 20 to page 9, line 4, Figure 1, ref. 14 and Figure 2, ref. 26.

³⁶ See *id.*, e.g., at page 5, lines 7-8 and Figure 1, ref. 17.

³⁷ See *id.*, e.g., at page 12, lines 15-22, page 13, lines 7-8 and Figure 6, ref. 100.

³⁸ See *id.*, e.g., at page 5, lines 20-21 and page 14, lines 9-13.

³⁹ See *id.*, e.g., at page 5, lines 4-5, page 8, lines 12-19, page 8, line 20 to page 9, line 23, Figures 1, 5 and 6, refs. 16 or 18 and Figures 2-3, refs. 28 or 30.

medical instrument,⁴⁰ wherein said using comprises affixing a strain gauge⁴¹ on an outer portion⁴² of the operative distal tip of the medical instrument in order to detect movement of the operative distal tip.⁴³

Dependent claim 17 recites the following:

The method of claim 15, wherein said affixing comprises affixing at least one other strain gauge on the outer portion of the flexible member of the medical instrument.

Dependent claim 23 recites the following:

The method of claim 14, wherein said affixing the strain gauge on the outer portion of the operative distal tip of the medical instrument in order to detect movement of the operative distal tip provides information regarding a location of the operative distal tip.⁴⁴

⁴⁰ See *id.*, e.g., at page 5, line 21 to page 22, line 3 and page 14, lines 14-17.

⁴¹ See *id.*, e.g., at page 5, lines 4-5, page 8, lines 12-19, page 8, line 20 to page 9, line 23, Figures 1, 5 and 6, refs. 16 or 18 and Figures 2-3, refs. 28 or 30.

⁴² See *id.*, e.g., at page 5, lines 4-5, page 8, lines 12-18 and Figures 1, 5 and 6, refs. 16 or 18.

⁴³ See *id.*, e.g., at page 5, lines 5-9, page 8, lines 13-14 and page 9, line 9 to page 12, line 8.

⁴⁴ See *id.*, e.g., at page 5, lines 5-9, page 8, lines 13-14, page 9, line 9 to page 12, line 8 and Figure 1, refs. 12, 14, 15, 16, 17, 18 and 20.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL
(37 C.F.R. § 41.37(c)(1)(vi))

- Claims 2, 3, 7-13 and 22 stand objected to because of informalities.
- Claims 1, 4 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,339,799 (“Kami”).
- Claims 2, 3, 5 and 7-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kami.

ARGUMENT
(37 C.F.R. § 41.37(c)(1)(vii))

I. The Applicant Requests Reconsideration Of The Objection To Claims 2, 3, 7-13 and 22

As an initial matter, a “fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification.” *See at* § 2173.01.

A. Claims 2 And 8

The Office Action objects to claims 2 and 8 because they “recite functional language unsupported by structure to produce such a function.” *See* November 18, 2008 Office Action at page 2. Notably, the Office Action cites absolutely no authority for this proposition. *See id.* Moreover, “[t]here is nothing inherently wrong with defining some part of an invention in functional terms.” *See* Manual of Patent Examining Procedure (MPEP) at § 2173.05(g). “Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439

F.2d 210, 169 USPQ 226 (CCPA 1971).” *See id.* Indeed, “Applicant **may use functional language**, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought.” *See* MPEP at § 2173.01 (emphasis added).

Further, the claim and the specification specifically recite that “a resistance of said **strain gauge** changes when said **flexible engaging member** deflects.” Clearly, the claim does, in fact, recite structure. Moreover, the Office Action has not provided any authority that precludes claims from reciting functional limitations. Indeed, as noted above, the MPEP specifically notes that such language is acceptable. Thus, for at least these reasons, the Applicant respectfully requests reconsideration of this claim objection.

B. Claims 3 And 9

The Office Action objects to claims 3 and 9 because they allegedly fail to “further limit the structure of the claimed invention.” In particular, the Office Action summarily concludes that “[c]laims 3 and 9 recite that the strain gauge is within an electrical circuit, which is considered to be an inherent feature of a strain gauge, and the remainder of the claim merely sets forth limitations placed upon the electrical circuit, which is not positively set forth as part of the inventive structure.” *See id.*

The Applicant does not necessarily concede that an electrical circuit is “necessarily” a feature of a strain gauge. Indeed, claim 3 recites that the strain gauge is within an electrical circuit. A strain gauge clearly can exist, by itself, outside of an electrical circuit. Further, even if one were to assume that an electrical circuit is an inherent component of a strain gauge, the

Office Action, once again, provides absolutely no authority for objecting to a claim because it recites an inherent feature. Moreover, the Office Action even acknowledges that the claim “sets forth limitations placed upon the electrical circuit.” As noted above, [t]here is nothing inherently wrong with defining some part of an invention in functional terms.” *See* Manual of Patent Examining Procedure (MPEP) at 2173.05(g). “Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).” *See id.* Thus, for at least these reasons, the Applicant respectfully requests reconsideration of these claim objections.

C. Claim 7

The Office Action states that [c]laim 7 is incomplete for lacking any element or structure that is capable of imaging to guide surgery as set forth in the preamble of the claim.” *See* November 18, 2008 Office Action at page 2. The Office Action provides not authority for this assertion. Indeed, the Office Action cites nothing that requires claims to be essentially engineering manuals that recite every possible part of a device. The Office Action also does not cite any authority that stands for the proposition that a recitation in a preamble of a claim requires that the remainder of claim recite particular limitations. Moreover, the claim **specifically recites** an “**image guided** surgery system comprising...at least one of an electromagnetic, optical, inertial position, and ultrasound **tracking system** configured to track said medical instrument.” Thus, despite the fact that the Office Action cites to no authority that supports the assertion noted above, the claim does, in fact, recite a “structure,” namely a “tracking system” that is “capable

of” image guided surgery. Thus, for at least these reasons, the Applicant respectfully requests reconsideration of this claim objection.

II. Kami Does Not Anticipate Claims 1, 4 And 6

“A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a **single prior art reference.**” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). “The **identical** invention must be shown in as complete detail as is contained in ... the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

“**All words in a claim must be considered** in judging the patentability of that claim against the prior art.” *In re Miller*, 441 F.2d 689, 694 (C.C.P.A. 1971) (quoting *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970) (emphasis added). “The functional language is, of course, an additional limitation in the claim.” *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999).

A. Claim 1

Claim 1 recites, in part, “a strain gauge affixed to an outer portion of said flexible engaging member, wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member.” Thus, the claim is clear that the strain gauge detects movement of the operative distal tip of the flexible engaging member.

Kami discloses a medical system including a “detector or pressure sensor for detecting a state of contact between the subject and the treatment section, and a reproduction mechanism for

amplifying a small contact pressure according to the output of the detector and thus reproduce the state of contact so that the surgeon can perceive the state of contact.” *See* Kami at Abstract.

The Office Action cites Kami at Figure 18 as disclosing “a strain gauge affixed to an outer portion of said flexible engaging member, wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member.” *See* November 18, 2008 Office Action at page 2. In particular, the Office Action cites to the laser probe 122 and the strain gauge 121 shown in Figure 18 of Kami. *See id.*

The Office Action states that the “laser probe is interpreted to constitute a needle by the common definition of that term as set forth by Merriam Webster (‘a slender pointed object resembling a needle’).” *See* November 18, 2008 Office Action at pages 2 and 5. However, the Office Action does not attach a copy of the definition of “laser probe,” nor does the Office Action cite to which “Merriam Webster” it refers. *See id.*

The Applicant is unable to find a definition of “laser probe” in Webster’s Collegiate Dictionary, 10th Ed. That dictionary does, however, define “laser” as a “device that utilizes the natural oscillations of atoms or molecules between energy levels for generating coherent electromagnetic radiation usu. in the ultraviolet, visible, or infrared regions of the spectrum.” *See* Webster’s Collegiate Dictionary, 10th Ed. At page 655 (attached). Clearly, a “laser” is by no means a “needle.” Further, a “probe” that emits a “laser” is also by no means a “needle.” In short, contrary to the assertion in the Office Action, the Applicant respectfully submits that a “laser probe” is not a “needle.”

As noted above, the Office Action relies on “laser probe 122” and “strain gauge 121.” See November 18, 2008 Office Action at page 2. Kami simply does not describe, teach or suggest that the strain gauge 121 is used to detect movement of the laser probe 122. Instead, Kami discloses the following:

Pressure sensors 125u, 125d, 125l, and 125r (125l is not shown) are installed inside the tip of the sheath 123 to detect whether the contact direction of the tip of the laser probe 122 is up, down, left, or right. A strain gauge 121 is installed to detect a pressure working when the laser probe 122 is placed on a tissue.

Kami at column 13, lines 1-6 (emphasis added). Kami is clear that the pressure sensors are used to detect whether the **contact direction** is up, down, left, or right. However, the strain gauge is used do “detect a pressure working when the laser probe 122 is placed on a tissue.” In particular, Kami discloses the following:

In this embodiment, an output of a strain gauge 121 is assessed to detect a pressure acting when a laser probe is in contact with a tissue. The pressure is reproduced in fingertips to be moved by driving fingertip members 130a to 130e.

Id. at column 13, lines 24-28. While the strain gauge 121 is used to detect pressure acting when a laser probe is in contact with a tissue, **Kami does not describe, teach or suggest that the strain gauge is used to detect movement of the laser probe.** Thus, Kami does not describe, teach or suggest “a strain gauge affixed to an outer portion of said flexible engaging member, wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member,” as recited in claim 1. Thus, for at least these reasons, Kami does not anticipate claims 1, 4 and 6.

The Office Action states, however, the following:

Examiner maintains the detection of the laser probe coming into contact with tissue does in fact constitute detection of the movement of the operative distal tip of the flexing engaging member – the **tip must inherently move in order to make contact with the tissue, thus detection constitutes detection of movement.**

See November 18, 2008 Office Action at page 5.

To recap, the Applicant previously demonstrated that Kami does not describe, teach or suggest “a strain gauge affixed to an outer portion of said flexible engaging member, wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member,” as recited in claim 1. See August 20, 2008 Amendment. In response to the August 20, 2008 Amendment, the Office Action seemingly concludes, without supporting references, that to the extent Kami does not disclose the limitations, they are “inherent.” Clearly, such a convenient assumption in response to a detailed demonstration set forth by the Applicant cannot establish a *prima facie* case of anticipation.

Notably, the Office Action provides absolutely no citation to any reference that discloses that a tip of a *laser probe* must inherently move in order to make contact with the tissue and that a strain gauge detects such movement. Instead, the Office Action merely conveniently makes the assumption noted above and that somehow this means that Kami anticipates the claims. However, the “fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” See *id. citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Applicant respectfully submits that neither Kami, nor the Office Action “make[s] clear that the missing descriptive matter,” *i.e.*, that a laser probe must inherently move in order to make contact with tissue and that such movement is detected by a strain gauge, “is **necessarily** present in” Kami.

A rejection based on inherency must be based on factual or technical reasoning:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.

Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The Applicant respectfully submits that the Office Action does not contain a basis in fact and/or technical reasoning to support the statement regarding inherency. Instead, as noted above, the Office Action merely summarily concludes that the “tip must inherently move in order to make contact with the tissue, thus detection constitutes detection of movement.” Even if such a summary conclusion was accurate, the Office Action has not shown that Kami discloses that the strain gauge detects movement of the tip. Further, as explained above, Kami discloses that “the strain gauge is used do “detect a pressure working when the laser probe 122 is placed on a tissue.” See Kami at column 13, lines 1-6. Thus, for at least these reasons, the Applicant maintains that Kami does not anticipate claims 1, 4 and 6 because it does not describe, teach or

suggest “a strain gauge affixed to an outer portion of said flexible engaging member, wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member,” as recited in claim 1.

B. Claim 4

Kami does not anticipate claim 4 for an additional reason. Claim 4 recites “wherein said flexible engaging member is one of a needle, catheter, curette, and K wire.” Figure 18 of Kami shows and describes, however, a “laser probe 122,” which is by no means a “needle, catheter, curette or K wire.”

The Office Action states that the “laser probe is interpreted to constitute a needle by the common definition of that term as set forth by Merriam Webster (‘a slender pointed object resembling a needle’). *See* November 18, 2008 Office Action at pages 2 and 5. However, the Office Action does not attach a copy of the definition of “laser probe,” nor does the Office Action cite to which “Merriam Webster” it refers. *See id.*

The Applicant is unable to find a definition of “laser probe” in Webster’s Collegiate Dictionary, 10th Ed. That dictionary does, however, define “laser” as a “device that utilizes the natural oscillations of atoms or molecules between energy levels for generating coherent electromagnetic radiation usu. in the ultraviolet, visible, or infrared regions of the spectrum.” *See* Webster’s Collegiate Dictionary, 10th Ed. At page 655 (attached). Clearly, a “laser” is by no means a “needle.” Further, a “probe” that emits a “laser” is also by no means a “needle.” In short, contrary to the assertion in the Office Action, the Applicant respectfully submits that a

“laser probe” is not a “needle.” Thus, for at least this additional reason, Kami does not anticipate, nor render unpatentable, claims 4 or 12.

III. Kami Does Not Render Claims 2, 3, 5 And 7-23 Unpatentable

As noted in the Manual of Patent Examining Procedure (Revision 7, July 2008), “[t]o establish *prima facie* obviousness of a claimed invention, **all the claim limitations** must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).” See MPEP at 2143.03 (emphasis added). Further, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA).” See *id.* (emphasis added). With these principles in mind, the Applicant now addresses the specific rejections of claims 7-23.

A. Independent Claims 7 And 14

Independent claim 7 recites, in part, “at least one strain gauge affixed to an outer portion of said flexible engaging member in order to detect movement of said deflectable operative distal tip.” Independent claim 14 recites, in part, “affixing a strain gauge on an outer portion of the operative distal tip of the medical instrument in order to detect movement of the operative distal tip,” as recited in claim 14. For at least the reasons discussed above with respect to claim 1, the Applicant respectfully submits that Kami does not render claims 7, 14 and the claims that depend therefrom unpatentable.

B. Claims 5 And 17

Claim 5 recites, in part, “at least one additional strain gauge affixed to said flexible engaging member.” Kami clearly does not describe, teach or suggest this limitation. Indeed, the

Office Action acknowledges that Kami “does not expressly teach a second strain gauge affixed to the laser probe.” *See* November 18, 2008 Office Action at page 3. Surprisingly, however, the Office Action goes on to state that the Applicant “does not disclose that the additional strain gauge solves a particular problem, is used for a specific purpose, or presents a patentable advantage over prior art single-gauge arrangements.” *See id.*

The Applicant respectfully disagrees. The specification of the present application is **replete with examples of the utility and advantages of additional strain gauges.** *See* present application, *e.g.*, at page 9, line 20 to page 12, line 14. As but one example, the specification clearly states that the “flexible member 14 may also have lateral strain gauges 46 [in addition to the upper strain gauge 16 and the lower strain gauge 18] affixed thereto **for providing additional information regarding lateral deflection** of the flexible engaging member 14.” *See id.* at page 12, lines 11-13 (emphasis added). Thus, the specification of the present application most certainly does describe that the additional strain gauge solves a particular problem, is used for a specific purpose **and** present a patentable advantage over single gauge arrangements. Thus, for at least these reasons, the Applicant respectfully submits that Kami clearly does not anticipate, nor render unpatentable, claims 5 and 17.

Nevertheless, the Office Action states that “Applicant admits that Kami (‘799) discloses multiple lateral pressure sensors that perform the same function as the recited strain gauges ([August 20, 2008 Amendment] p. 7 paragraphs 1-2).” *See* November 18, 2008 Office Action at page 5. With all due respect, the Applicant makes no such admission. *See* August 20, 2008 Amendment at page 7. As noted above, Kami is clear that the **pressure sensors** are used to

detect whether the **contact direction** is up, down, left, or right. Kami at column 13, lines 1-6. Detecting whether contact **direction is up, down, left, or right** is not necessarily the same as “detecting **movement** of said operative distal tip of said flexible engaging member,” as recited in claim 1, for example. The Applicant respectfully submits that Kami does not describe a strain gauge or any other pressure sensor that detects movement of an operative distal tip of a flexible engaging member. As noted above, the specification of the present application clearly sets forth advantages of using multiple strain gauges to detect such movement. Thus, the Applicant respectfully maintains that Kami does not render claims 5 and 17 unpatentable for at least this additional reason.

C. Claims 7 And 20

The Applicant respectfully submits that Kami does not render claims 7 and 20 for an additional reason. Claim 7 recites, in part, “at least one of an electromagnetic, optical, inertial position, and ultrasound tracking system configured to track said medical instrument.” The Office Action cites Kami at column 19, lines 8-37 and Figure 38 as disclosing an “optical system that is capable of tracking the position of the laser probe.” *See* November 18, 2008 Office Action at page 4.

The Applicant notes, however, that **the embodiment shown in Figure 38 of Kami does not include the laser probe.** Thus, the embodiment shown in Figures 38 does not track a laser probe. Further, the “optical system” shown in Figure 38 is “for a main unit 302 of an intraoperative **microscope**.” *See* Kami at column 19, lines 31-32 (emphasis added). Kami does not describe, teach or suggest that this microscope **tracks a laser probe**. That is, Kami does not

disclose that the “microscope” is “at least one of an electromagnetic, optical, inertial position, and ultrasound tracking system configured to track said medical instrument,” as recited in claim 7, for example. Thus, for at least these reasons, the Applicant respectfully submits that Kami does not render claims 7 and 20 unpatentable.

The Office Action asserts, however, the following:

Kami ('799) explicitly states that “[i]ntraoperative microscopes permitting surgery under microscope observation realize precise operation... the intraoperative microscope allows a surgeon to proceed in a surgical procedure” (col. 19 lines 11-14). Through at least this disclosure, Kami ('799) clearly **anticipates** performing a surgical operation, including the one described elsewhere in the reference using the laser probe, under microscope observation.

See November 18, 2008 Office Action at pages 5-6. Notably, the cited portion of Kami states that “[i]ntraoperative microscopes permit[] surgery under microscope observation” and “the intraoperative microscope allows a surgeon to proceed in a surgical procedure without distracting his/her visual line.” See Kami at column 19, lines 11-16. There is absolutely nothing in Kami that describes, teaches or suggests, however, that the “intraoperative microscope” is configured or used to track a medical instrument. Thus, the Applicant maintains that Kami does not render claims 7 and 20 unpatentable for at least this additional reason.

D. Claims 21 And 22

Claim 21 recites, in part, “wherein said strain gauge provides information regarding a location of said operative distal tip in relation to a longitudinal axis of said support member.” Claim 22 recites, in part, “wherein said at least one strain gauge provides information regarding a location of said deflectable operative distal tip.”

The Office Action rejects these claims as follows:

Regarding claims 21 and 22, the strain gauge of Kami ('799) provides information regarding a location of the deflectable operative distal tip in relation to a longitudinal axis of the support member as previously discussed in claim 1.

See November 18, 2008 Office Action at page 4. Notably, the Office Action does not provide any explanation as to how its reasoning with respect to claim 1 is applicable to the specific limitations of claims 21 and 22. Indeed, the Office Action does not provide any citation from Kami that describes, teaches or suggests "wherein said strain gauge provides information regarding a location of said operative distal tip in relation to a longitudinal axis of said support member," as recited in claim 21, or "wherein said at least one strain gauge provides information regarding a location of said deflectable operative distal tip." Thus, for at least these reasons, the Applicant respectfully submits that the Office Action has not established that Kami renders claims 21 and 22 unpatentable.

E. Claim 23

Claim 23 recites, in part, "wherein said affixing the strain gauge on the outer portion of the operative distal tip of the medical instrument in order to detect movement of the operative distal tip provides information regarding a location of the operative distal tip." The Office Action merely cites to Kami at column 13, lines 1-6 as disclosing this limitation. However, this cited portion of Kami discloses the following:

Pressure sensors 125u, 125d, 125l, and 125r (125l is not shown) are installed inside the tip of the sheath 123 to detect whether the contact direction of the tip of the laser probe 122 is

up, down, left, or right. A strain gauge 121 is installed to detect a pressure working when the laser probe 122 is placed on a tissue.

Kami at column 13, lines 1-6 (emphasis added). Kami is clear that the **pressure sensors** are used to detect whether the **contact direction** is up, down, left, or right. However, the strain gauge is used do “detect a pressure working when the laser probe 122 is placed on a tissue.” There is nothing in this cited portion of Kami that describes, teaches or suggests that the strain gauge 121 “provides information regarding a location of the operative distal tip” or the laser probe 122. Thus, for at least this reason, the Office Action has not shown that Kami renders claim 23 unpatentable.

V. CONCLUSION

For at least the reasons discussed above, the Applicant respectfully submits that the pending claims are allowable in all respects. Therefore, the Board is respectfully requested to reverse the rejections of pending claims 1-23.

PAYMENT OF FEES

The Commissioner is authorized to charge any necessary fees, including the \$30 fee for the Notice of Appeal and the \$540 fee for this Appeal Brief, or credit overpayment to Deposit Account 50-2401.

Dated: January 14, 2009

Respectfully submitted,
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CLAIMS APPENDIX
(37 C.F.R. § 41.37(c)(1)(viii))

1. A medical instrument for use in an image guided surgery system, comprising:

a support member operatively connected to a flexible engaging member having an operative distal tip; and

a strain gauge affixed to an outer portion of said flexible engaging member, wherein said strain gauge detects movement of said operative distal tip of said flexible engaging member.
2. The medical instrument of claim 1, wherein a resistance of said strain gauge changes when said flexible engaging member deflects.
3. The medical instrument of claim 2, wherein said strain gauge is within an electrical circuit in which a potential difference occurs when said resistance of said strain gauge changes.
4. The medical instrument of claim 1, wherein said flexible engaging member is one of a needle, catheter, curette, and K wire.
5. The medical instrument of claim 1, further comprising at least one additional strain gauge affixed to said flexible engaging member.
6. The medical instrument of claim 1, wherein said portion of said flexible engaging member is proximate to said support member.

7. An image guided surgery system, comprising:
 - a medical instrument having a flexible engaging member operatively connected to a support member, said flexible engaging member having a deflectable operative distal tip;
 - at least one of an electromagnetic, optical, inertial position, and ultrasound tracking system configured to track said medical instrument; and
 - a deflection tracking system configured to track said flexible engaging member of said medical instrument, said deflection tracking system comprising at least one strain gauge affixed to an outer portion of said flexible engaging member in order to detect movement of said deflectable operative distal tip.
8. The image guided surgery system of claim 7, wherein a resistance of said at least one strain gauge changes when said flexible engaging member moves.
9. The image guided surgery system of claim 8, wherein said at least one strain gauge is within an electrical circuit in which a potential difference occurs when said resistance of said strain gauge changes.
10. The image guided surgery system of claim 9, further comprising a processing unit that correlates said potential difference with an amount of movement of said flexible engaging member.
11. The image guided surgery system of claim 7, further comprising a display for showing a position of said medical instrument within an operating area of a patient.

12. The image guided surgery system of claim 7, wherein said flexible engaging member is one of a needle, catheter, curette, and K wire.

13. The medical instrument of claim 7, wherein said portion of said flexible engaging member is proximate to said support member.

14. A method of navigating a medical instrument having a flexible engaging member having an operative distal tip, the method comprising:

tracking the medical instrument with a first position tracking method that tracks a proximal end of the medical instrument; and

using a second tracking method to track movement of the operative distal tip of the medical instrument, wherein said using comprises affixing a strain gauge on an outer portion of the operative distal tip of the medical instrument in order to detect movement of the operative distal tip.

15. The method of claim 14, comprising measuring a change in voltage that arises from a change in resistance of the strain gauge upon deflection of the operative distal tip.

16. The method of claim 15, wherein said affixing comprises affixing the strain gauge on the portion of the flexible engaging member that is proximate a support member of the medical instrument.

17. The method of claim 15, wherein said affixing comprises affixing at least one other strain gauge on the outer portion of the flexible member of the medical instrument.

18. The method of claim 15, further comprising correlating the change in voltage to an amount of deflection of the flexible engaging member.

19. The method of claim 14, further comprising combining data received from said tracking and using and displaying a position of the medical instrument based on the combined data.

20. The method of claim 14, wherein said first tracking method comprises one of an electromagnetic, optical, inertial position and ultrasound tracking method.

21. The medical instrument of claim 1, wherein said strain gauge provides information regarding a location of said operative distal tip in relation to a longitudinal axis of said support member.

22. The image guide surgery system of claim 7, wherein said at least one strain gauge provides information regarding a location of said deflectable operative distal tip.

23. The method of claim 14, wherein said affixing the strain gauge on the outer portion of the operative distal tip of the medical instrument in order to detect movement of the operative distal tip provides information regarding a location of the operative distal tip.

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EVIDENCE APPENDIX
(37 C.F.R. § 41.37(c)(1)(ix))

- (1) U.S. 5,339,799 (“Kami”), entered into record by Examiner in May 28, 2008 Office Action.
- (2) Webster’s Collegiate Dictionary, 10th Ed., page 655, entered into record by Applicant in this Appeal Brief.

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RELATED PROCEEDINGS APPENDIX
(37 C.F.R. § 41.37(c)(1)(x))

Not applicable.



Merriam-Webster's Collegiate[®] Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

